Eur J Vasc Endovasc Surg **11**, 308–314 (1996)

Walking Ability and Quality of Life as Outcome Measures in a Comparison of Arterial Reconstruction and Leg Amputation for the Treatment of Vascular Disease

Maximiano Albers*, Ayrton C. Fratezi and Nelson De Luccia

Department of Surgery, Division of Vascular Surgery, University of São Paulo Medical School, São Paulo, Brazil

Objectives: *To compare the walking ability and the quality of life of patients with severe limb ischaemia treated with an arterial reconstruction (AR) or a primary below-knee amputation (BKA).*
Design: *A cohort study of patients with the first episode of ischaemia.*
Setting: *University tertiary referral centre.*
Patients: *Thirty-eight (AR 22, BKA 16) patients were studied over a 12-month period with a complete follow-up.*
Chief outcome measures: *Walking ability was assessed with a subjective scale and quality of life was measured with the Spitzer QL-INDEX. The results were assessed for patients still alive (Step 1) as well as for all patients (Step 2).*
Results: *Walking ability was better in the AR group at 3 (OR = 10.37; CI 2.12, 50.74; p = 0.004), 6 (OR = 6.47; CI 1.83, 22.79; p = 0.004), and 12 (OR = 3.82; CI 1.20, 12.15; p = 0.03) months. Quality of life was significantly better for AR patients at 3 (OR = 4.32; CI 1.55, 12.02; p = 0.005) and 6 (OR = 4.40; CI 1.68, 11.53; p = 0.003) months, but not at 12 months (OR = 2.44; CI 0.95, 6.26; p = 0.06). The 12 month foot salvage rate was 68%.*
Conclusion: *Walking ability and quality of life are better for AR patients than for BKA patients, even with a moderate foot salvage rate.*

Key Words: Arterial occlusive diseases; Quality of life; Walking ability; Bypass graft; Critical limb ischaemia.

Introduction

Arterial reconstruction for the treatment of severe limb ischaemia is performed to relieve rest pain, to promote ulcer healing, to limit tissue loss and to preserve bipedal gait. This procedure is therefore aimed at preserving or restoring the health-related quality of life to the best possible level. In this context, vascular surgeons have used outcome measures such as functional health,[1] independent mobility,[2–5] walking ability,[2] and quality of life[2,6,7] as parameters for determining the success of intervention. As a result, there is already considerable body of information on the management of peripheral arterial disease.[1,2,4,6,8–10] These measures may also be useful for decision analysis,[3,7] economic evaluation,[11,12] and auditing,[13] activities in which arterial reconstruction is of particular interest. Since graft patency rates decrease with time, while the rehabilitation status of patients with an amputation often improves,[14] a comparison of arterial reconstruction and major amputation should be done over a reasonable period of time. The aim of this study on chronic severe leg ischaemia was therefore to carry out a 12 month comparison of the walking ability and the quality of life of patients undergoing an arterial reconstruction (AR) or a primary below-knee amputation (BKA).

*Please address all correspondence to: Maximiano Albers, MD, Rua Ministro Godói, 1584, apto 74, São Paulo, SP ZIP 05015-001, Brazil.

Patients and Methods

Study design

A cohort strategy was used to reduce selection bias, to evaluate multiple outcomes, and to assess the results repeatedly. The choice of a 12 month period of observation was based on other publications.[7,15–17]

Patient selection

On a previous study,[18] the walking ability and the

1078–5884/96/030308 + 07 $12.00/0

quality of life of 100 patients have been measured at baseline and reassessed 3, 6 and 12 months later, according to a standardised follow-up. The following entry criteria had been adopted: (1) an age of 40 years or more, (2) palpable femoral but absent pedal pulses, (3) the presence of rest pain, non-healing ulceration or gangrene, (4) no previous episode of severe ischaemia in the affected limb, and (5) the absence of cancer or mental disorders. The files of 38 of the original 100 patients were used in this study and corresponded to 22 AR and 16 BKA performed within 60 days of entering the study. Sixty-two patients were not considered in this study for various reasons, of which the most important was a physical handicap in 19 (contralateral major amputation in 11; stroke in 8). Another 36 patients were excluded because of an alternative initial treatment (conservative management in 16, lumbar sympathectomy in 1, minor amputation in 12, through-knee amputation in 1, and above-knee amputation in 6). The remaining seven patients were excluded because they underwent arterial reconstruction or leg amputation more than 60 days after initial assessment.

Table 1. Risk factors and variables of interest at baseline

	AR group (n=22)	BKA group (n=16)
Age (years)		
Range	40–83	40–83
First quartile	54	58
Median	60.5	64
Third quartile	70	70
Men	16	11
Smoking	16	9
Diabetes	6	8
Uraemia*	2	6
Heart disease	10	10
Infected ulcer/gangrene	7	9
Ankle-pressure (mmHg)		
Range	30–110	0–90
First quartile	40	35
Median	50	50
Third quartile	70	60
Odds ratio	1.00	1.55
QL-INDEX score		
Range	2–5	2–6
First quartile	3	2.5
Median	4	3
Third quartile	5	6
Odds ratio	1.00	1.41

*p=0.05, Fisher exact test.

Patient characteristics

There was no important difference between the two groups with regard to age and sex, or in the degree and extent of smoking, diabetes, heart disease, and foot infection. The difference in ankle systolic blood pressure and in quality of life was also not important. However, the prevalence of an abnormal renal function was significantly higher in the BKA group than in the AR group (Table 1).

Surgical treatment

The 22 arterial bypass grafts consisted of one iliacofemoral, 14 femoropopliteal (above-knee, 5; below-knee, 9) and seven infrapopliteal (anterior tibial, 4; peroneal, 3). Three AR patients required a secondary reconstruction which included two femoropopliteal bypasses (above-knee, 1; below-knee, 1), and one thrombectomy with reanastomosis. Of the 16 BKA patients, 11 healed without complications while five underwent a secondary amputation (below-knee, 1; through-knee, 4).

Outcome variables

The chief outcome variables were walking ability and quality of life, but graft patencies, foot salvage, and patient survival were also assessed.[19] Walking ability was classified as absent, assisted (the need for canes, frames or crutches), or free (no need for walking aids),[6] as shown in Table 2. Quality of life was measured with the Spitzer QL-INDEX.[20] This index is a simple, concise, valid and reliable tool for the overall

Table 2. Walking ability in subgroups AR1 and AR2, and in the BKA group (Step 1)

	3 months			6 months			12 months		
	AR		BKA	AR		BKA	AR		BKA
Walking ability	AR1	AR2		AR1	AR2		AR1	AR2	
Absent	4	4	14	1	4	10	1	3	7
Assisted	5	–	2	5	–	6	3	1	7
Free	6	–	–	9	–	–	9	1	2
Died	1	2	–	1	2	–	2	2	–

	3 months	6 months	12 months
A. AR vs. BKA			
Odds ratio	10.37	6.47	3.82
CI	2.12–50.74	1.83–22.79	1.20–12.15
Chi-squared	8.344	8.436	5.147
p-value	0.004	0.004	0.03
B. AR1 vs. BKA			
Odds ratio	20.75	32.33	9.80
C. AR2 vs. BKA			
Odds ratio	nd	nd	0.72

nd, not determined.

Table 3. QL-INDEX scoring for subgroups AR1 and AR2 and in the BKA group (Step 1)

	Baseline		3 months			6 months			12 months		
	AR	BKA	AR		BKA	AR		BKA	AR		BKA
Score			AR1	AR2		AR1	AR2		AR1	AR2	
1	–	–	–	–	1	–	–	–	–	–	–
2	1	4	–	2	2	–	1	1	–	1	–
3	8	5	–	1	1	–	–	1	–	1	4
4	8	2	1	1	8	–	3	6	–	3	3
5	5	4	4	–	3	2	–	5	2	–	4
6	–	1	5	-	1	2	-	3	3	–	2
7	–	–	2	–	–	2	–	–	2	–	3
8	–	–	2	–	–	5	–	–	4	–	–
9	–	–	–	–	–	2	–	–	2	–	–
10	–	–	1	–	–	2	–	–	–	–	–

	Baseline	3 months	6 months	12 months
A. AR vs. BKA				
Odds ratio	1.41	4.32	4.40	2.44
CI	0.54–3.63	1.55–12.02	1.68–11.53	0.95–6.26
Chi-squared	0.499	7.849	9.062	3.482
p-value	0.48	0.005	0.003	0.06
B. AR1 vs. BKA				
Odds ratio		25.87	22.70	8.89
C. AR2 vs. BKA				
Odds ratio		0.21	0.15	0.22

measurement of quality of life and can be administered by the vascular surgeon himself in about 1 min.[6] The index evaluates five dimensions: (1) involvement in own occupation (Occupation), (2) activities of daily living (ADL), (3) perception of own health (Health), (4) support of family and friends (Support), and (5) outlook on life (Outlook). The timeframe is the week before examination and each dimension is scored 0, 1 or 2 so that the highest attainable score is 10. One of the authors (ACF), who was not involved in patient care, assessed all of the 38 patients during 142 medical interviews with 100% complete follow-up.

Statistical analyses

The Step 1 analysis of walking ability and quality of life was restricted to patients still alive (Tables 2 and 3). In Step 2, patients already dead were also considered when measuring quality of life, with the last score obtained before death used at all the subsequent points in time for which a reassessment had been planned (Table 4). AR patients were further classified into subgroups AR1 (no major amputation) or AR2 (with a secondary major amputation) to allow for secondary analysis. A procedure described by Morton and Dobson[21] was adopted to compute the odds ratios where appropriate. The use of 95% confidence intervals (CI)[22] and hypothesis testing was restricted to the main objectives. The Mann-Whitney test was preferred in order to avoid the assumption of normality.

Results

Clinical course

In the AR group, the 12 month cumulative primary, secondary and tertiary graft patency rate was 50, 54 and 59%, respectively. Of the 22 AR patients, seven (2 deaths) had no tissue loss, eight underwent minor amputation, five (1 death) had a below-knee amputation, and two (1 death) had an above-knee amputation. At 12 months, the cumulative foot salvage rate was 68% and the patient survival rate was 82%. In the BKA group, the final amputation was below-knee for 12 patients and through-knee for the other four, with no deaths.

Walking ability

Walking ability improved with time in both the AR and the BKA groups but was significantly better for

Table 4. QL-INDEX scoring for subgroups AR1 and AR2 and in the BKA group (Step 2)

	Baseline		3 months			6 months			12 months		
	AR	BKA	AR		BKA	AR		BKA	AR		BKA
Score			AR1	AR2		AR1	AR2		AR1	AR2	
1	–	–	–	–	1	–	–	–	–	–	–
2	1	4	–	2	2	–	1	1	–	1	–
3	8	5	–	2	1	–	1	1	–	2	4
4	8	2	2	2	8	1	4	6	1	4	3
5	5	4	4	–	3	2	–	5	2	–	4
6	–	1	5	-	1	2	-	3	3	–	2
7	–	–	2	–	–	2	–	–	2	–	3
8	–	–	2	–	–	5	–	–	4	–	–
9	–	–	–	–	–	2	–	–	2	–	–
10	–	–	1	–	–	2	–	–	1	–	–

	Baseline	3 months	6 months	12 months
A. AR vs. BKA				
Odds ratio	1.41	3.24	3.05	1.97
CI	0.54–3.63	1.23–8.57	1.19–7.85	0.82–4.76
Chi-squared	0.499	5.629	5.371	2.280
p-value	0.48	0.02	0.02	0.13
B. AR1 vs. BKA				
Odds ratio		17.58	15.71	6.75
C. AR2 vs. BKA				
Odds ratio		0.27	0.15	0.21

the AR group. The walking ability for BKA patients was worst at 3 months, but improved at 6 and 12 months (Table 2). The walking ability in the BKA group was worse than in the AR1 subgroup but better than in the AR2 subgroup. Throughout the study, however, the difference between AR1 and BKA patients decreased while that between AR2 and BKA patients increased. As a result, the overall difference between the AR and BKA groups decreased progressively (Table 2).

Quality of life

There was a significantly worse quality of life for BKA patients at 3 and 6 months, but not at 12 months. The magnitude of the risk, however, was always higher than the risk of 1.41 measured at baseline (Tables 3 and 4). The quality of life in the BKA group was worse than in the AR1 subgroup, with a difference that decreased from three to 12 months. However, the quality of life was uniformly better in the BKA group than in the AR2 subgroup throughout the study. It must be remembered in this regard that the QL-INDEX score always reflects the summation of its individual components.

The risk of a worse outcome in the BKA group was increased in four of the five dimensions of the QL-INDEX. Occupation showed the greatest increase in all the three assessments, with 7–11 out of 16 AR1 patients achieving 1 or 2 points, while only one of 16 BKA patients and none of the AR2 patients did the same. Support, on the other hand, was largely invariant, since almost all the patients achieved two points in all three assessments. Finally, the risk increased moderately for ADL and Outlook, but only a little for Health (Table 5).

The confounding effect of renal function

The risk of a worse walking ability in the BKA group was smaller for patients with abnormal renal function at 6 and 12 months. On the other hand, the risk of a worse quality of life in these patients was always greater. In both cases, however, the resulting confounding effect was small (Table 6).

Discussion

Walking ability was better in the AR group than in the BKA group because of a much better outcome for AR1 patients. However, some BKA patients had a better walking ability than certain AR1 patients (Table 2).

Table 5. Scores for the individual components of the QL-INDEX (Step 2)

		3 months			6 months			12 months		
		AR		BKA	AR		BKA	AR		BKA
	Points	AR1	AR2		AR1	AR2		AR1	AR2	
A. Occupation										
	0	9	6	15	5	6	15	6	7	15
	1	5	–	1	8	–	1	7	–	1
	2	2	–	–	3	–	–	2	–	–
AR vs. BKA*				7.13			15.27			10.54
B. ADL										
	0	1	6	12	–	6	8	–	7	7
	1	12	–	4	9	–	8	10	–	9
	2	3	–	–	7	–	–	5	–	–
AR vs. BKA*				6.86			3.83			2.38
C. Health	0	1	4	2	1	2	1	1	1	2
	1	11	2	14	4	4	13	2	6	9
	2	4	–	–	11	–	2	12	–	5
AR vs. BKA*				1.28			2.65			1.80
D. Support										
	0	–	–	1	–	–	–	–	–	1
	1	–	–	1	–	–	–	–	–	–
	2	16	6	14	16	6	16	15	7	15
AR vs. BKA*				nd			nd			nd
E. Outlook										
	0	–	2	3	–	1	2	–	2	3
	1	12	4	13	9	5	14	7	5	10
	2	4	–	–	7	–	–	8	–	3
AR vs. BKA*				4.31			10.00			2.26

nd, not determined.
*The estimates are odds ratios.

Table 6. The influence of renal function on the risk of a worse walking ability or quality of life for BKA patients*

	Renal function	3 months	6 months	12 months
A. Walking ability				
(Step 1)	Normal	8.33	5.50	4.12
	Abnormal	nd	5.00	1.33
	All	10.37	6.47	3.82
B. Quality of life				
(Step 1)	Normal	2.81	4.24	2.20
	Abnormal	nd	10.00	8.00
	All	4.32	4.40	2.44
(Step 2)	Normal	2.07	2.52	1.69
	Abnormal	nd	10.00	4.00
	All	3.24	2.63	1.97

nd, not determined.
*The estimates are odds ratios.

Thus, foot salvage, an anatomical outcome, is not sufficient for a better physical rehabilitation. Similarly, walking ability, a physically related outcome, cannot capture other important aspects of human life. For this latter reason, a measure of quality of life is also desirable.

Quality of life was better for the AR group, but the difference between AR and BKA patients was lower than it was in walking ability, probably as a result of the contribution of social and emotional domains. This finding therefore strengthens the need for considering health-related quality of life in the field of infra-inguinal arterial reconstruction. As for walking ability, AR1 patients scored the highest for quality of life whereas AR2 scored the lowest. This result not only supports the belief that a failed bypass graft is more harmful than a primary amputation but also estimates the decreased risk of BKA in relation to AR2 at 12 months as being 0.22 (Table 3) or 0.21 (Table 4). This latter finding is more related to some components of the QL-INDEX than to others.

Occupation was the component most responsible for the difference in quality of life between AR and BKA patients. The wide difference in this dimension, observed within as early as 3 months, is in agreement with the opinion that the QL-INDEX would improve should Occupation be replaced by Independence on mobility,[23] a relevant dimension for patients with arterial disease.[2,24] Another problem was the invalidity and the insensitivity to change already identified for Support[23,25]; the other three dimensions conveyed more useful information.

The fluctuations in ADL, Health, and Outlook reflected a good sensitivity to change, although they did not follow a uniform pattern throughout the study. In brief, all the components, except for Support, showed a lower increased risk for the BKA group at 12 months, as was also observed for walking ability and quality of life. The changes in the individual components in the same direction as that of the global score is evidence for the appropriateness of the QL-INDEX.[26] Although this index should be modified, its current form still provides important information. The possibility of biased information, however, must be considered for any index or profile, particularly in nonrandomised comparisons.

There are several indications that a sample selection bias was avoided in this study. First, the differences between the groups were reduced with a prospective design and strict entry criteria. Second, correcting for the increased risk of 1.41 for a worse quality of life at baseline would yield an odds ratio still greater than 2.0 at 3 and 6 months and close to 1.40 at 12 months (Step 2). Third, the absence of deaths or above-knee amputations indicated that BKA patients had a lower risk than usual since the expected rate for these events was 11 and 22%, respectively.[3] Finally, the 18% mortality rate combined with the 59% tertiary graft patency rate at 12 months indicated that the AR patients were high risk. Although selection bias was unlikely, other forms of bias are worth considering.

Our past experience with the QL-INDEX has been satisfactory,[6,18] but information bias dependent on this measuring tool or arising from the use of a single rater is impossible to evaluate. Indeed, there are conflicting findings on inter-observer agreement with the QL-INDEX and other tools.[20,27] The fact that the rater in this study was a vascular surgeon is another potential source of bias. Although self-assessment of quality of life has been recommended,[26,27] we preferred to use interviews because of the limitations of old age, low literacy, and potential visual impairment. In addition, the advantages of a maximal response rate, no missing items, and minimal errors of misunderstanding must also be considered.[28] Finally, sample distortion bias was avoided by using a standardised follow-up that was 100% complete.

Confounding and chance also deserve some consideration. Confounding attributable to renal function in the association between treatment and chief outcomes was small. Furthermore, chance was not the explanation for the association between treatment and walking ability. This was also true for quality of life at 3 and 6 months, although not at 12 months. Thus, in the absence of either bias the internal validity of this study was not compromised. The external validity also seems acceptable.

In conclusion, arterial reconstruction has a favourable influence on walking ability and quality of life when compared to primary leg amputation. This superiority depends heavily on avoiding a major amputation in most patients. These statements are valid only for the first episode of severe leg ischaemia in patients with an intact contralateral limb and free of stroke.

The main implication arising from the results of this study is that measuring quality of life is promising as a uniform approach for testing the effectiveness of arterial reconstruction in situations in which a low foot salvage rate is expected. Such situations include multiple failed bypasses, advanced distal disease, patients at high risk or a combination of these.[29] For example, using the data shown in Table 4 we can estimate a 12 month foot salvage rate of 44% as the limit at which AR and BKA patients would have the same 12 month score for quality of life. This estimate is in disagreement with the 25% rate postulated on subjective grounds in a consensus document.[25]

References

1 Schneider JR, McHorney CA, Malenka DJ, McDaniel MD, Walsh DB, Cronenwett JL. Functional health and well-being in patients with severe atherosclerotic peripheral vascular occlusive disease. *Ann Vasc Surg* 1993; **7**: 419–428.

2 Regensteiner JG, Hargarten ME, Rutherford RB, Hiatt WR. Functional benefits of peripheral vascular bypass surgery for patients with intermittent claudication. *Angiology* 1994; **44**: 1–10.

3 Michaels JA. The selection of amputation level: an approach using decision analysis. *Eur J Vasc Surg* 1991; **5**: 451–457.

4 Hehir DJ, Cross KS, Colgan MP, Moore DJ, Shanik GD. Improved limb salvage and mobility following peroneal artery bypass. *Eur J Vasc Surg* 1994; **8**: 332–334.

5 Hosie KB, Kockelberg R, Newbury-Ecob RA, Callum KG, Nash JR. A retrospective review of the outcome of patients over 70 years of age considered for vascular reconstruction in a district general hospital. *Eur J Vasc Surg* 1990; **4**: 313–315.

6 Albers M, Fratezi AC, De Luccia N. Assessment of quality of life of patients with severe ischemia as a result of infrainguinal arterial occlusive disease. *J Vasc Surg* 1992; **16**: 54–59.

7 Tröeng T, Bergqvist D, Janzon L, Jendteg S, Lindgren B. The choice of strategy in the treatment of intermittent claudication — a decision tree approach. *Eur J Vasc Surg* 1993; **7**: 438–443.

8 Arfvidsson B, Karlsson JK, Dahlöf A-G, Lundholm K, Sullivan M. The impact of intermittent claudication on quality of life evaluated by the Sickness Impact Profile technique. *Eur J Clin Invest* 1993; **23**: 741–745.

9 De Luccia N, Pinto MAGS, Guedes JPB, Albers MTV. Rehabilitation after amputation for vascular disease: a follow-up study. *Prosthet Orthotics Int* 1992; **16**: 124–128.

10 Pell JP, Donnan PT, Fowkes FG, Ruckley CV. Quality of life following lower limb amputation for peripheral arterial disease. *Eur J Vasc Surg* 1993; **7**: 448–451.

11 Katz DA, Cronenwett JL. The cost-effectiveness of early surgery versus watchful waiting in the management of small abdominal aortic aneurysms. *J Vasc Surg* 1994; **19**: 980–991.

12 Allen D, Ferguson M, Chant T. Cost effectiveness of treating critical ischaemia using quality adjusted life years. *Br J Surg* 1990; **77**: A348.

13 Bergqvist D, Tröeng T, Einarsson E, Elfström J, Norgren L. Vascular surgical audit during a 5-year period. *Eur J Vasc Surg* 1994; **8**: 472–477.

14 Robbs JV, Human RR, Rajaruthnam P. Bypass versus primary major amputation in patients with femoropopliteal distal disease and a threatened limb. *S Afr Med J* 1984; **66**: 809–812.

15 Wolfe JHN. Defining the outcome of critical ischaemia: a one year prospective study. *Br J Surg* 1986; **73**: 321.

16 Tröeng T, Bergqvist D, Janzon L. Incidence and causes of adverse outcomes of operation for chronic ischaemia of the leg. *Eur J Surg* 1994; **160**: 17–25.

17 Consensus document. *Eur J Vasc Surg* 1992; **6(SA)**: 1–32.

18 Fratezi AC. Estudo da evolução clínica e da qualidade de vida em isquemia grave do membro inferior. Comparação de doentes com e sem diabetes. *Doctoral Thesis*, pp **89**. São Paulo, 1993.

19 Rutherford RB, Flanigan DP, Gupta SK *et al.* Suggested standards dealing with lower extremity ischemia. *J Vasc Surg* 1986; **4**: 80–94.

20 Spitzer WO, Dobson AJ, Hall AJ *et al.* Measuring the quality of life of cancer patients: a concise QL-INDEX for use by physicians. *J Chron Dis* 1981; **34**: 585–597.

21 Morton AP, Dobson AJ. Analysing ordered categorical data from two independent samples. *Br Med J* 1990; **301**: 971–973.

22 Kramer MS. Statistical inference for categorical variables. In: Kramer MS, ed. *Clinical epidemiology and biostatistics. A primer for clinical investigators and decision-makers*. 1st ed. New York: Springer Verlag, 1988: 165–186.

23 Morris JN, Suissa S, Sherwood S, Wright SM, Greer D. Last days: a study of the quality of life of terminally ill cancer patients. *J Chron Dis* 1986; **39**: 47–62.

24 Cheshire NJW, Wolfe JHN, Noone MA, Davies L, Drummond M. The economics of femorocrural reconstruction for critical leg ischemia with and without autologous vein. *J Vasc Surg* 1992; **15**: 167–175.

25 Mor V. Cancer patients' quality of life over the disease course: lessons from the real world. *J Chron Dis* 1987; **40**: 535–544.

26 Fletcher A, Gore S, Jones D, Fitzpatrick R, Spiegelhalter D, Cox D. Quality of life measures in health care. II: Design, analysis, and interpretation. *Br Med J* 1992; **305**: 1145–1148.

27 Slevin ML, Lynch D, Drinkwater J, Gregory WM. Who should measure quality of life, the doctor or the patient? *Br J Cancer* 1988; **57**: 109–112.

28 Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. *Ann Intern Med* 1993; **118**: 622–629.

29 Skillman JJ. It can be fixed, but should it be? *Ann Surg* 1993; **218**: 713–714.

Accepted 7 June 1995